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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/762,926 | 06/11/2001 | Joelle Thonnard | BM45330 | 9849 |

25308 7590 03/25/2003

DECHERT

ATTN: ALLEN BLOOM, ESQ
4000 BELL ATLANTIC TOWER
1717 ARCH STREET
PHILADELPHIA, PA 19103

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/25/2003

93

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/762,926 | THONNARD, JOELLE |
| | Examiner | Art Unit |
| | Khatol S Shahnan-Shah | 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 November 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 59 and 69-91 is/are pending in the application.
- 4a) Of the above claim(s) 59,70,72,73,75,78,79 and 81-91 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 69,71,74,76,77 and 80 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment C and response of October 22, 2002, paper No. 11 is acknowledged. Claims 29-35, 37, 39-42 and 57 were canceled by the applicant. New claims claims 69-91 were added. Specification page 1 was amended.
2. Applicant's IDS of October 22, 2002, paper No. 12 is acknowledged. The references have been considered by the examiner, see attached form 1449.
3. Applicant's typographical error in regard to serial No. of the application in the response and IDS has been corrected by the office. The application No in some pages of the amendment and IDS was typed as 09/762,976 instead of 09/762,926.
4. The status of claim 59 has not been addressed by the applicant. Claim 59 is withdrawn from consideration as being drawn to non-elected group II. (Note applicant canceled all other claims, which were drawn to non-elected inventions except claim 59). This issue was addressed in the previous office action. Applicant has not responded to its status. Clarification is requested.
5. Claims 59 and 69-91 are pending in this application.
6. Newly added Claims 69, 71, 74, 76, 77 and 80 are drawn to polypeptides and fusion protein. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 59, 70, 72, 73, 75, 78, 79 and 81-91 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
7. Claims 69, 71, 74, 76, 77 and 80 are under consideration.

Prior Citations of Title 35 Sections

8. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

9. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

Objections Withdrawn

10. Objection to the specification, made in paragraph 7 of the office action mailed 8/13/2002, paper #10 is withdrawn in view of applicant's amendments. The priority statement has been added.

11. Objection to the specification, made in paragraph 9 of the office action mailed 8/13/2002, paper #10 is withdrawn in view of applicant's amendments. A brief description of the drawings has been added.

12. Objection to the abstract, made in paragraph 5 of the office action mailed 8/13/2002, paper #10 is withdrawn in view of applicant's amendments. An abstract of disclosure has been added.

Objections Maintained

13. Objections to the drawings made in paragraph 8 of the office action mailed 8/13/2002, paper #10 are maintained. No amendments to the drawings were submitted. Applicants response of 8/13/2002 has been noted but has not been persuasive.

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The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “fig 1 and fig 2 ” has been used to designate SEQ ID NOS 1, 2 and 3. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

14. Objections to the specification in regard to use of trademarks made in paragraph 9 of the office action mailed 8/13/2002, paper #10 are maintained. No amendments or response were submitted.

Rejections Moot

15. Rejection of claims 29-35, 37, 39-42 under 35 U.S.C. 112, first paragraph made in paragraph 10 of the office action mailed 8/13/2002, paper #10 is moot in view of applicant’s cancellation of the claims.

16. Rejection of claims 37, 42 and 57 under 35 U.S.C. 112, second paragraph made in paragraph 11 of the office action mailed 8/13/2002, paper #10 is moot in view of applicant’s cancellation of the claims.

17. Rejection of claims 29, 37, 39, 40 and 41 under 35 U.S.C. 102 (b) made in paragraph 13 of the office action mailed 8/13/2002, paper #10 is moot in view of applicant’s cancellation of the claims.

18. Rejection of claim 57 under 35 U.S.C. 102 (b) made in paragraph 14 of the office action mailed 8/13/2002, paper #10 is moot in view of applicant’s cancellation of the claim.

19. Rejection of claims 29-32, 37, 39, 40 and 41 under 35 U.S.C. 102 (b) made in paragraph 15 of the office action mailed 8/13/2002; paper #10 is moot in view of applicant's cancellation of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

20. Claims 69, 71, 74, 76, 77 and 80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

Claims 69, 71, 74, 76, 77 and 80 recite a polypeptide comprising a member selected from an immunogenic polypeptide comprising a fragment sequence of at least 15 or 20 amino acids that matches an identically aligned contiguous segment of SEQ ID NO: 4.

The specification and the claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims include numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is highly variant, SEQ ID NO: 4 is insufficient to describe the genus or fragments thereof. Applicant's recitation that the fragment or variant has the ability to generate antibodies to SEQ ID NO: 4 is noted, however this is a function of any peptide. Every peptide of at least 10 amino acids is capable of eliciting an antibody, and if the full length protein is linearized the elicited antibody will also

bind the full length protein. Thus applicant has not described a function, which is shared by the full length or fragments thereof of SEQ ID NO: 4, which would adequately describe the genus. One skilled in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus of the variants. Thus applicant was not in possession of the claimed genus.

None of these fragments meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116).

Art Rejections

21. Note: Prior to setting forth the art rejections it is noted that the priority document United Kingdom 9818004.5 filed 8/18/1998 does not have written description support for the newly claimed invention. Accordingly, the prior art date is the International filing date of 8/13/1999. Should applicant wish to dispute the assignment of the date of the invention, he/she should point to the sections in the priority document for written description support for the now claimed invention.

Claim Rejections - 35 USC § 102

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22. Claims 69, 71, 74, 76 and 80 are rejected under 35 U.S.C. 102(a) as being anticipated by Massignani et al. (WO9924578) prior art made of record applicant's IDS PTO form 1449.

The claims are drawn to an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acid that matches an identically aligned contiguous segment of SEQ ID NO: 4.

Massignani et al. teach an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acid that matches an identically aligned contiguous segment of SEQ ID NO: 4. (see Accession Numbers AAY38937, AAY38938, AAY38939, AAY38940, in attached sequence alignment and abstract, claim 4 pages 474, 477, 479 and 480 of WO9924578).

Massignani et al. teach proteins isolated from *Neisseria meningitidis* (strains A and B) having 97% identity with SEQ ID NO: 4 of the present invention. Massignani et al. also teach fusion proteins (see page 4).

The prior art teaches the claimed product.

Since the office does not have the facilities for examining and comparing applicants' products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

23. No claim is allowed.
24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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March 24, 2003

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LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600